

Pennsylvania State University Tobacco Center of Regulatory Science

Reduced Nicotine Cigarettes in Smokers with Mood and Anxiety Disorders (Project 2)

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Abstract:

The overall aim of this proposed study is to evaluate the effect of progressive nicotine reduction in cigarettes on smoking behavior, toxin exposure and psychiatric symptoms in smokers with comorbid mood and/or anxiety disorders. To do so, we will randomly assign 200 adult smokers with a unipolar mood and/or anxiety disorder within the past year to smoke research cigarettes that will contain either a) Usual Nicotine Content (UNC): nicotine content similar to their preferred usual brand of cigarettes; or b) Reduced Nicotine Content (RNC): the nicotine content per cigarette is progressively reduced from approximately 11 mg to 0.3 mg over 5 months. All subjects will participate in lead-in periods prior to randomization to assess normal smoking behavior and to establish ability to tolerate research cigarettes prior to randomization. It is our hypothesis that nicotine intake, as measured by plasma cotinine concentration, will decline as a function of cigarette nicotine content in the RNC group. Further, it is our hypothesis that by gradually reducing the nicotine content of the cigarettes on a monthly basis, there will not be significant increases in biomarkers of tobacco smoke exposure, severity of nicotine withdrawal symptoms, mood and anxiety symptomatology or protocol non-adherence over time in the experimental group (RNC) as compared with the UNC control group.